The Examiner has objected to or rejected original claims 1-31 variously under 35 U.S.C. §112, first and second paragraphs, §102 and under the judiciallyi created doctrine of obviousness-type double patenting as being invalid for the reasons which have been stated in the office action. Applicants will address each of the Examiner's rejections in the sections which follow. The objection to claim 1 because of its presentation with a typographical error has been obviated with the cancellation of claim 1 and the presentation of new claims 32-39. This objection will not be further discussed.

The §112, First and Second Paragraph Rejections

Under paragraph 3a of the office action, the Examiner has rejected claims 21, 23-27 and 31, because Applicant had failed to include an affidavit supporting the deposit. In order to address the Examiner's rejection, Applicants enclose herewith the declaration of Professor Angel Lopez (one of the co-inventors of the present application). Applicants separately note the presentation of information in the specification on page 23, disclosing the date of deposit and the name and address of the depository as requested by the Examiner.

Under paragraph 3b and 3c, the Examiner has rejected originally filed claims 1-12, 14-20, 22 and 24-30 under 35 U.S.C. §112, first paragraph for the reasons which are detailed in the office action. These relate to enablement and written description concerns. Applicants note that they have modified and narrowed the scope of the originally filed claims and new claims 32-39 present these claims in a manner which address and are in compliance with the Examiner's comments. Note that claims 32 and 33 have been restricted to the common receptor β_c and to antibodies or fragments thereof that bind both the B'-C' loop and the F'-G' loop. It is respectfully submitted by Applicants that there is exemplification in the specification of a monoclonal antibody as well as fragments thereof. Regarding the hybridoma cell line subject of claim 34, this is specifically enabled by the deposit which was made and is described in the specification on page 23. Claim 35 is directed to a method of isolating other inhibitors and is restricted to the common receptor β_c and to antibodies or fragments thereof that bind both the B'-

C' loop and the F'-G' loop. It is respectfully submitted that this claim is fully supported and enabled by the description on page 22 of the specification.

Turning to the remaining claims, claims 36-37 have been restricted to a method of inhibiting leukaemic cell proliferation, and claims 38-39 have been restricted to the action of monoclonal antibodies or fragments thereof on eosinophils. It is respectfully submitted that the examples which are set forth on pages 18-22 of the specification fully support these claims. 36-39, these claims have been

It is respectfully submitted, with the presentation of the instant amendment, the claims provide a scope commensurate with the experimental data of the examples and therefore meet the requirements of 35 U.S.C. §112 with respect to enablement and written description requirements.

Regarding the Examiner's rejection of the originally filed claims under 35 U.S.C. §112, second paragraph, it is respectfully submitted that with the cancellation of claims 1-31 and the presentation of new claims 32-29, any further discussion of this rejection has been rendered moot.

It is respectfully submitted that, for the foregoing reasons, the claims meet the requirements of 35 U.S.C. §112, first and second paragraphs.

The Obviousness-type Double Patenting Rejection

Turning to the Examiner's obviousness-type double patenting rejection, because the claims have been amended significantly from their original scope, it is respectfully submitted that this rejection may no longer be applicable in the present application.

The §102 Rejections

The Examiner has presented arguments in the office action that the claims are anticipated accordingly by several references which have been presented. Applicants acknowledge the Examiner's rejections and respectfully respond as follows.

Regarding paragraph 6a, the Examiner objects that certain claims are anticipated by WO 97/28190 ("WO28190"). Applicants respectfully submit that in that reference there is no disclosure whatsoever of an antibody or fragments thereof that bind to both the F'-G' and the B'-C' loop. Although WO28190 discloses an antibody that binds the F'-G' loop, there is no disclosure of an antibody that binds both the F'-G' and B'-C'loops. That restriction is present in each of the proposed new claims either directly or indirectly.

In that regard we note that the current model generally accepted as being the structure of β_c is based on physical data derived from the interaction of Growth Hormone with Growth Hormone receptor (Bagley *et al*, Blood, 1997 vol 89 pp 1471-1482, copy enclosed). We point out however that in contradistinction with the model, the binding of a ligand in β_c does not appear to involve the E-F loop. Accordingly, although it is perhaps predicted that the F'-G' loop and the B'-C'- loops are juxtaposed in the β_c, as with the GHR, there is no data at the priority date which shows that that is the case in β_c. It is therefore non-obvious that a single antibody is capable of binding both loops, thus rendering the present claims patentable over the cited prior art.

Turning to paragraph 6b of the office action, Applicants respectfully submit that the proposed new claims are not anticipated by US patent 6,200567, for similar reasons set out with respect to paragraph 6a, above. In short, there is no teaching that a single antibody is capable of binding both loops.

With regard to the Sun *et al.,* disclosure, Applicants provide the following. Although

there is reference to the subject antibodies and hybridomas, neither the monoclonal antibody nor the hybridoma for producing the antibody were made available by the inventors. Accordingly, while there is brief reference that the antibody QP1 (BION-1) did have certain effects, without the antibody, these effects could not possibly be achieved.

The detail of where the antibody bound has not been disclosed in Sun *et al.*, beyond that it bound to domain 4. There is thus no disclosure of an antibody that binds the F'-G' and the B'-C' loop. Without the antibody, it is respectfully submitted that there is no way that such an inherent property of the BION-1 antibody could be ascertained and consequently, Sun, *et al* could not be seen as disclosing the present invention.

With respect to claims 36 through 39, the Sun *et al.*, abstract speculates about a possible clinical significance for allergy, and refers in very short form to an inhibition of TF1.8 cells. Furthermore the abstract does not, for example, show an effect on eosinophils. Clearly the Sun, *et al.* reference does not anticipate claims 36-39 of the present application.

Consequently, it is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. For the above reasons, Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

Applicant has cancelled 31 claims (5 independent) and added 8 claims (all independent). A fee in the amount of $126.00 for three additional independent claims is believed to be due for the presentation of this amendment. A petition for an extension of time of three months is also enclosed as is a check in the amount of $591.00 (extension plus additional claims). A small entity form is on file in the present application. Applicants attach an appendix which sets for the amendments made to the originally filed claims. An information disclosure statement and cited references are also enclosed.

Respectfully submitted,

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Dated: February 11, 2003

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C., 20231, on February 11, 2003.

_____
Henry D. Coleman (Reg. No. 32,559)

Appendix
S.N. 09/762,963

The following amendment is made to the originally filed application.

In the Specification

On page 1, after the title, the following is added:

--RELATED APPLICATIONS

This application is a §371 of PCT application number PCT/AU99/00659, filed 13 August 1999.--

In the Claims:

Cancel claims 1-31 and add the following claims 32-39.

32. A monoclonal antibody or fragments thereof capable of inhibiting the binding of cytokines IL-3, GM-CSF and IL-5 to the common receptor β_c, wherein the monoclonal antibody or fragments thereof binds to both the B'-C' loop and the F'-G' of domain 4 of the β_c subunit.

33. A monoclonal antibody produced by the hybridoma cell line deposited as accession number ATCC HB-12525.

34. The hybridoma cell line ATCC HB-12525.

35. A method of identifying an inhibitor capable of competitively inhibiting the binding of

BION-1 to the β_c subunit, the method including the steps of contacting BION-1 or fragment thereof with the β_c subunit as well as a candidate inhibitory compound,

and the step of measuring the degree of binding of BION-1 to the β_c subunit, and comparing it to the degree of binding in the absence of the candidate inhibitory compound.

36. A method of inhibiting the IL-5, IL-3 or GM-CSF mediated leukaemic cell proliferation by contacting the leukaemic cells with monoclonal antibody or fragments thereof capable of inhibiting the binding of cytokines IL-3, GM-CSF and IL-5 to the common receptor β_c, wherein the monoclonal antibody or fragments thereof binds to both the B'-C' loop and the F'-G' of domain 4 of the β_c subunit.

37. A method of inhibiting the IL-5, IL-3 or GM-CSF mediated leukaemic cell proliferation as in claim 36 wherein the monoclonal antibody or fragments thereof are BION-1 or fragments thereof.

38. A method of inhibiting IL-5, IL-3 or GM-CSF mediated oesinophil activation, oesinophil production or oesinophil survival, by contacting the oesinophils with monoclonal antibody or fragments thereof capable of inhibiting the binding of cytokines IL-3, GM-CSF and IL-5 to the common receptor β_c, wherein the monoclonal antibody or fragments thereof binds to both the B'-C' loop and the F'-G' of domain 4 of the β_c subunit.

39. A method of inhibiting IL-5, IL-3 or GM-CSF mediated oesinophil activation, oesinophil

production or oesinophil survival, as in claim 38 wherein the monoclonal antibody or fragments thereof are BION-1 or fragments thereof.